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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

July 21, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. William R. Lance, D.V.M.
President
Wildlife Pharmaceuticals, Inc.
1401 Duff Drive, Suite 700
Fort Collins, CO 80524

PURGED

Ref.# - DEN-99-14

Dear Dr. Lance:

During an inspection of your veterinary drug manufacturing facility conducted January 26 through February 17, 1999, by Investigator Michael J. Kuchta and Microbiologist Jeannette A. Schmieg, it was found that your firm has been commercially marketing veterinary drugs without approval of supplemental new animal drug applications for a change in manufacturing facilities and for revisions in manufacturing procedures as required by Title 21, Code of Federal Regulations, Part 514.8. Such deviations cause these veterinary drugs manufactured at this facility to be adulterated within the meaning of section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). Specifically, the following deviations were noted:

1. [redacted]
NADA [redacted]

[redacted] lots of [redacted] have been manufactured at your Ft. Collins, CO, facility since March, 1997, however, no supplemental new animal drug application has been approved for manufacturing this product at the Ft. Collins location. The originally approved NADA allowed only for the contract manufacturing of this product by [redacted]. [redacted] of these [redacted] lots have been commercially distributed. Your original supplement for this site change, submitted June 11, 1997, was found incomplete and you were so notified by letter dated December 11, 1997, from the Center for Veterinary Medicine, Office of New Animal Drug Evaluation. That letter further stated that based on the incomplete nature of the supplement, the proposed change could not be legally implemented.

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2. [redacted]
NADA [redacted]

One lot of [redacted] was manufactured at the Ft. Collins, CO, facility in August, 1997, however, a supplemental new animal drug application was not submitted for this manufacturing site change until after the current inspection. That supplement is currently under review and has yet to be approved. A portion of this lot has been commercially distributed.

3. [redacted]
NADA [redacted]
[redacted]
NADA [redacted]

In 1998, a new cleanroom and air handling system for parenteral drug processing and filling was constructed at the Ft. Collins facility. This new filling suite was qualified and released for production in October, 1998, with single lots of [redacted] manufactured between October, 1998 and January, 1999. NADA supplements reporting this manufacturing change were not submitted until after the current inspection.

We acknowledge receipt of your March 5, 1999 response to the FD-483 which addresses the above issues as well as GMP deficiencies noted during the inspection. In your response you report that supplements have been submitted for the above changes. Your proposed corrections to the noted GMP deficiencies, along with further corrections submitted to this office on May 25, 1999, appear to address our concerns and will be evaluated during the next inspection.

However, I would like to emphasize that the focus of this Warning Letter is your apparent disregard for the drug approval process. Despite the fact your products target minor species and minor uses, it is adherence to the scientific principles fostered through the drug approval process that establishes confidence in your products and processes. Without this scientifically based assurance, neither the Food and Drug Administration nor you can speak with authority to the safety and efficacy of your products.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Also include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to the Food and Drug Administration, Denver District Office, Attention: H. Tom Warwick, Compliance Officer. Mr. Warwick may be reached at (303) 236-3054 if you have further questions regarding this letter.

Sincerely,

Gary C. Dean
District Director